

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments, the further declaration of Dr. Cornett with supporting data and scientific publication, and in view of the reasons that follow. Claims 8 and 17 are currently being amended. This amendment changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. After amending the claims as set forth above, claims 1-5, 8-13, 15-31, 33-35, 38 and 44-57 are now pending in this application.

Claims 17 and 18

Claims 17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for allegedly failing to describe an inducible viral promoter or inducible epithelial cell specific promoter. As the Examiner has stated the specification on pages 20 and 21 disclose inducible promoters and additionally, the specification discloses tissue-specific promoters on page 21, as referenced in Burcin *et al.* However, in an effort to expedite prosecution, claim 17 has been amended to depend from claim 8, and applicants believe that this amendment obviates this rejection. Withdrawal of the rejection of claims 17 and 18 is kindly requested.

Claims 1-5, 8-13, 15-31, 33-35, 38 and 44-57

Claims 1-5, 8-13, 15-31, 33-35, 38 and 44-57 remain rejected under 35 U.S.C. §112, first paragraph, for allegedly not containing subject matter which was described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Applicants respectfully traverse this rejection.

The Examiner states that applicants' previous response and Dr. Cornett's previous declaration are insufficient to overcome the rejection of claims. The Examiner states that Figure 1 cited in Dr. Cornett's declaration and relied upon by applicants was not attached to his declaration. Applicants confirm that indeed Figure 1 was attached to Dr. Cornett's

October 16, 2003 declaration, and in support of this statement, Applicants have attached a copy of the date stamped postcard from the Patent Office that shows under Item 3 that a declaration with Exhibits A-C was submitted.

Applicants herewith attach a further declaration by Dr. Cornett, in which he provides the previously submitted Figure 1 that was attached to his declaration of October 16, 2003 and attests that the presently attached Figure 1 was the same Figure 1 that was previously submitted. Dr. Cornett's new declaration explains the data that was summarized previously in Figure 1 and the data not shown, supports his arguments with scientific publications, and provides additional data showing the expression of β 2AR in allergen sensitized Brown-Norway rats that is a model animal system utilized by scientists in the field to study the airway disease, asthma.

Applicants submit that Dr. Cornett's present declaration addresses the issues raised by the Examiner as allegedly in support of his lack of enablement rejection. Dr. Cornett's present declaration with supporting Attachments 1 and 5 provide data that show that airway resistance is decreased and thus airway diameter is increased in normal rats and in an allergen sensitized rat model. Applicants have provided evidence of expression of the β 2AR gene in accepted animal models by way of evidence of airway dilation (as measured by decreased airway resistance) as compared to untreated control animals. See particularly ¶¶ 6 and 9 of Dr. Cornett's declaration.

Applicants submit that the cited publications of Orkin and Demoly may address the issue of replacing a defective gene, however, Dr. Cornett's declaration addresses this negativity and further explains that the present invention supplements or augments the endogenous β 2AR already present in the subject's body. In fact, two later review articles by Dr. Factor support Dr. Cornett's statement regarding the issues raised in these publications. Dr. Factor recognized that supportive therapy was useful for providing evidence of airway dilation by the expression of β 2AR (See ¶ 12 of Dr. Cornett's declaration).

Applicants respectfully request that the Examiner consider the above arguments that refer to the attached declaration by Dr. Cornett as well as this further declaration by Dr. Cornett with accompanying figures supporting the expression of β 2ARs in cells of the rat lung along with the supporting scientific publications that provide evidence of the enablement

of the presently claimed invention. In view of these arguments, it is requested that this rejection be withdrawn.

Applicants kindly request that if any documents are not attached that are referred to in the present response or declaration, the Examiner should contact the undersigned attorney and she will have documents faxed directly to the Examiner.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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